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TITLE: Successful Strategies for Activity and Wellness after Spinal Cord Injury

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RECIPIENT: Palo Alto Veterans Institute for Research
Palo Alto, CA 94304

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14. ABSTRACT The purpose of this study is to identify best practices for overcoming and adapting one's life to spinal cord injury (SCI). This study takes a more positive point of view and identifies strategies that enable persons living with SCI to successfully navigate the barriers and limitations. Our goal is to better understand the motivations, practices, and strategies used by people with SCI to combat inactivity and achieve healthier lifestyles. Through this reporting period, recruitment for year one is 92% complete (37/40) with 25% of transcript analysis accomplished. Staff training in qualitative research and use of mind mapping software has been completed with rapid progress being made on data analysis. Patient-centered summaries and cross-interview codes are being developed and discussed in preparation to designing the codebook to be implemented toward identification of Key Themes which is the primary activity for the next quarter. Recruitment for Phase 2 (mixed qualitative and quantitative study to apply findings of Phase 1) is 90% complete and a testing schedule is in progress.					
15. SUBJECT TERMS Paralysis, Physical Activity, Qualitative Research, Lifestyle, Social Participation, Health Behavior					
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- 1. INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

The purpose of this study is to identify best practices for overcoming and adapting one's life to spinal cord injury (SCI). After SCI, many people reduce their levels of physical activity which contributes to weight gain and greater risk of diabetes and cardiovascular disease and overall decreased quality of life; this effect is compounded with aging. Prior studies have identified the barriers people with SCI face to participating in activity such as transportation problems, limited availability of accessible facilities, and low motivation and body image. Nonetheless, there are many people with SCI who find ways around these hurdles and adopt active lifestyles despite their disability. Rather than focusing on the barriers and limitations of persons living with SCI, we plan to take a more positive point of view and look for the "success stories," that is, people who have identified strategies that enable them to successfully navigate the barriers. The overarching goal of this study is to better understand the motivations, practices, and strategies used by people with SCI to combat inactivity and achieve healthier lifestyles. This information can be then be incorporated into clinical and therapeutic support programs to motivate those who are less active.

- 2. KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Paralysis
Physical Activity
Qualitative Research
Lifestyle
Social Participation
Health Behavior

- 3. ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

Major Goals/Specific Aims:

- 1) Obtain community/stakeholder input and define activity paradigm.
Completion projected – Month 3; Expected Month 15.
- 2) Obtain information on attitudes toward wellness and strategies for being active by use of qualitative methods. Completion projected - Month 12; Expected Month 15.
- 3) Evaluate similarities and differences in behavioral and psychosocial constructs between persons with SCI who are active in the community and those who are not active; Explore physical, physiologic, and health correlates that may (i) correspond with self-perception of activity and (ii) differ between individuals with SCI who are active and those who are not.
Completion (i) projected – Month 15; Expected Month 18
Completion (ii) projected – Month 24

Milestones – Year 2	Projected Completion	% Complete
1) Publication of results	24 month	80%
2) Report to stakeholder/community and VA professional groups	24 month	100%
3) Compile findings and input from various sources; generate an integrated plan (“roadmap”) based on the identified strategies and success stories	24 month	75%
4) Complete proposal(s) for follow-on studies to validate survey findings in a larger population and evaluate a behavioral therapy approach	24 month	N/A

What was accomplished under these goals?

Accomplishments are presented in alignment with the Statement of Work (SOW) approved at study initiation. As reported in the Quarterly Reports, we have experienced delays from the initiation. The majority of study activities have been completed by Month 24; interpretation of results and dissemination are in process. Second year activities were focused on completion of Study 2, but completion of Study 1 was also accomplished in this period. Key Outcomes that were not reported in the 2015 Annual Report (ie, not completed due to study delays) are summarized here.

STUDY 1. QUALITATIVE STUDY

Specific Aim 2: Obtain information on attitudes toward wellness and strategies for being active by use of qualitative methods.

Major Activities

Task 6. Complete data collection, target total is 40 individuals.

Specific Objectives

Complete enrollment, interviews, review of transcripts, and data entry into spreadsheet.

Key Outcomes

- Interviews, including participation in focus groups, have been completed on 55 individuals who are representative of a breadth of demographics. This included practitioner groups of psychologists and recreation therapists as well as community recreation and therapeutic support personnel.
- Demographic information for the 37 individuals with SCI is presented below:

Gender	Injury Level	Age	SCI Duration	Veteran Status
Male 70%	Tetraplegia 54%	< 50 49%	≤ 6 years 22%	Veteran 51%
Female 30%	Paraplegia 46%	≥ 50 51%	> 6 years 78%	Non-Vet 49%

Task 7. Complete data analysis, analyze, interpret findings, and disseminate findings.

Specific Objectives

Complete data analysis, analyze, interpret findings, and disseminate findings

Key Outcomes

- All coding has been completed and codebooks developed with team discussion and processing.
- It is noted that numerous additional information has been generated for future processing beyond the original focus of activity and wellness, based on these very rich and comprehensive interviews.
- Key themes have been identified including:
 - definition of “being active” is much broader than staying fit or athletic;
 - home-based exercise programs and tools, often home-crafted, are much more common than anticipated;
 - for some, there is a strong belief that intense exercise will promote recovery;
 - self-efficacy and internal motivation (“believing they can”) are important factors;
 - capability for planning; and
 - support from others, often in the community beyond family, is an important factor
- Dissemination includes presentations at SCI professional conferences (2016 ASCIP accomplished, abstracts to be submitted for 2017 ASCIP and ISCoS), VA SCI/D Center staff meetings, and the local community peer group meetings.
- Manuscript submissions in process, described below.

STUDY 2. MIXED METHODS STUDY

Specific Aim 3 – Evaluate similarities and differences in behavioral and psychosocial constructs between persons with SCI who are active in the community and those who are not active.

Specific Aim 4 – Explore physical, physiologic, and health correlates that may (i) correspond with self-perception of activity; (ii) differ between individuals with SCI who are active and those who are not.

Note: Concurrent qualitative and quantitative methods (mixed methods approach) will be used to address Specific Aims 3 and 4. The types of assessment and analyses will differ, but the timing of work will overlap; therefore most of the Tasks listed below pertain to both Aims

Major Activities

Task 1. Project Planning for Study 2

Specific Objectives

- a. Develop structured questionnaires and select outcome measures, based on findings from focus groups and semi-structured interviews
- b. Train staff on measurement protocols and data collection procedures

Key Outcomes

- Findings from Study 1 focus groups and semi-structured interviews of a broad spectrum of stakeholders were reviewed and discussed among the multidisciplinary research team members for identification of measurable outcomes
- Existing outcome measures (previously selected and submitted in the original grant application) were reviewed for relevance to desired outcome measures, based on Study 1 findings
- Several measures were eliminated and others amended to reduce redundancy; several measures were added. The full packet was reviewed and pilot-tested for validity and participant burden.
- Staff members were trained on survey delivery (self-administered and phone) and database entry protocols.

Task 2. Study initiation

Specific Objectives

- a. Recruit participants into two groups by self-identification of activity status.
- b. Begin data collection of quantitative measures (field-based assessments), concurrent with interviews and field observations, target is 30 individuals.

Key Outcomes

- Participant recruitment included persons who had participated in Study 1, responses to flyers, and referrals from SCI/D Center clinical personnel with a focus on inclusion of a sample of persons who self-identify as “non-active.”
- Data collection was begun, with an IRB amendment to conduct all assessments in the laboratory.

Task 3. Interim analysis

Specific Objectives

- a. Project planning review meeting: take stock of data and deltas
- b. Workshop to review early indicators from physiologic study to help orient the direction of remaining interviews and upcoming coding parameters; implement changes in qualitative methods, if needed

Key Outcomes

Based on the systematic review of qualitative information and key themes from Study 1, it was decided that these objectives were not necessary.

Goals Not Met

Interim Analysis was determined to be unnecessary to meet project objectives. This was not done.

Task 4. Study completion.

Specific Objectives

- a. Complete data collection, expected total of 30 individuals.
- b. Data Analysis: analyze and code the data corpus, weekly progress meetings.
- c. Workshop on qualitative research findings.
- d. Generate manuscript(s) based on findings.

Key Outcomes

- 30 individuals have been identified for recruitment and 19 enrolled (63%) with data collection completed on 15 (50%).
- Workshop presentation at the 2016 annual scientific conference of the Academy of Spinal Cord Injury Professionals (ASCIP) entitled, “Practice Makes Perfect: Qualitative Research in Spinal Cord Injury Healthcare.” This workshop focused on methodology and the role of stakeholder participants throughout the process. Preliminary study data were presented.
- Two manuscript drafts are underway with expected submission in January 2017. Titles are: “Stakeholder perspectives on activity and participation after spinal cord injury” and “Activity and wellness after spinal cord injury: Key themes and strategies.”

Goals Not Met

1. Data collection and analysis is ongoing and expected to be completed early in 2017.
2. Manuscript submission has not been accomplished on the planned schedule.

Specific Aim 5 – Develop a roadmap of strategies that can be used by a diverse SCI population to achieve an active lifestyle and maintain wellness

Major Activities

Task 1. Evaluate findings compiled from both studies; apply cognitive behavioral theoretical models

Specific Objectives

Evaluate findings compiled from both studies; apply cognitive behavioral theoretical models.

Key Outcomes

- Interpretation of stakeholder perspectives are presented in the context of the International Classification of Functioning, Disability, and Health (ICF Model) forms the basis of for manuscript (#1), in preparation. Key themes are applicable as Personal and Environmental Factors, per the ICF Model, will provide evidence for therapeutic and psychosocial interventions
- Application of Grounded Theory is the basis of presentation of findings in the manuscript (#2) in preparation.

Goals Not Met

Completion of this task is delayed, pending completion of for Study 2 findings and data analysis.

Task 2. Report findings of research to SCI Community Research Advisory Board

Specific Objective

Report findings of research to SCI Community Research Advisory Board.

Key Outcomes

None to report at this time.

Goals Not Met

Completion of this task is delayed, pending completion of data analysis and Advisory Board meeting.

Task 3. Present findings of research to VA SCI Center colleagues and other professionals. Discuss applications of results and potential changes in practice.

Specific Objectives

Present research findings to clinical colleagues and discuss application of results.

Key Outcomes

- The PI has participated in SCI/D Center interdisciplinary team meetings focused on the need to better track and monitor activity status and productive work for Veteran patients with SCI. The context of these meetings has been compliance with Medical Rehabilitation Standards of the Commission for Accreditation of Rehabilitation Facilities (CARF). These discussions resulted in expansion of the definition of activity and "productive work (per CARF) to include “meaningful” work; team members included case managers, psychologists, physician and nurse managers, and social workers.
- Pilot testing of a patient survey on activity (time spent and type) has begun in conjunction with a quality improvement project supported by the SCI/D Center clinical team. It is noted that findings from this study are of high relevance to this clinician-generated project to evaluate the clinical needs of the patient population with especial attention to psychosocial support.

Task 4. With input from the SCI Community Research Advisory Board, discuss the design of a survey based on inputs from qualitative study to validate findings within a larger SCI population

Specific Objectives

Obtain input from SCI Community Research Advisory Board on survey design.

Key Outcomes

None to report at this time

Goals Not Met

Completion of this task is delayed, pending completion of data analysis and Advisory Board meeting.

Task 5. With input from VA clinicians, discuss design of a VA Rehabilitation R&D Merit Review proposal to develop rehabilitation therapy employing behavioral cognitive models to improve community reintegration of veterans with SCI, specifically related to engagement in community activity

Specific Objectives

With input from VA clinicians, discuss design of a VA Rehabilitation R&D Merit Review proposal to develop rehabilitation therapy to improve community reintegration engagement in community activity for veterans with SCI.

Key Outcomes

Based on discussion with VA clinicians, the immediate outcome will be expansion of monitoring of community activity/engagement of Veteran patients in order to better identify gaps in clinical services and needs of patients. The clinical team has incorporated our findings into a Quality Improvement Project to gather information from patients. These findings will provide evidence for next directions and whether a grant submission is warranted at this time.

Other Achievements: Based on engagement with clinical staff during focus groups and data processing, we expect to accomplish direct translation of findings through quality improvement and thus generate evidence to support clinical practice.

What opportunities for training and professional development has the project provided?

The study was not designed to provide training and professional development opportunities.
Nothing to Report

How were the results disseminated to communities of interest?

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

- 1) Complete and submit two manuscripts based on Study 1 findings.
- 2) Complete data collection and analysis for Study 2.
- 3) Disseminate findings as conferences in 2017 – Academy of SCI Professionals (ASCIP) and International Spinal Cord Society (ISCoS).
- 4) Complete and submit manuscript based on Study 2 findings
- 5) Coordinate with SCI/D Center clinical team to integrate findings into practice.

- 4. IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?

Findings from this study have been incorporated into a Clinical Quality Improvement Project to facilitate clinical monitoring of compliance with CARF Standards

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report – as we are in data analysis phase of project.

We anticipate that our findings will have a significant impact on improving knowledge on attitudes regarding participation and community integration. We further expect that our findings can be incorporated into the clinical support provided by psychosocial clinicians and therapists in the outpatient and acute inpatient setting as well as recreation therapy programming in the community. It is our expectation that improved community participation will be associated with better health and enhanced quality of life.

- 5. CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change

Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them

As previously reported, there was an initial delay in hiring of program staff due to administrative issues. This effectively delayed the project start by approximately one quarter. Other factors have further delayed achievement of some milestones on target. The project was originally proposed and funded as a two year study, but the approved project period was three years. Our plan for the final year is to complete study activities with available dedicated staff and no extension of funding.

Changes that had a significant impact on expenditures

No ongoing effect on expenditures.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

None

Significant changes in use or care of vertebrate animals.

Not Applicable. No use of vertebrate animals.

Significant changes in use of biohazards and/or select agents

Not Applicable. No use of biohazards.

6. PRODUCTS: List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”

- **Publications, conference papers, and presentations**

Conference presentation: 2016 Academy of SCI Professionals (ASCIP) Workshop/Podium Presentation entitled, “Practice Makes Perfect: XXX,” presented by Jenny Kiratli, Brinda Dalal, and Jessica Greene.
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Books or other non-periodical, one-time publications.

Nothing to Report

Other publications, conference papers, and presentations.

Nothing to Report

- **Website(s) or other Internet site(s)**

Nothing to Report

- **Technologies or techniques**

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: *Beatrice Jenny Kiratli*

Project Role: *Project Director/Principal Investigator*

Researcher Identifier (e.g. ORCID ID): *N/A*

Nearest person month worked: *2*

Contribution to Project: *Oversight of all study-related activities; position development and hiring activities; IRB submissions, communications with local R&D committee; interactions with DoD; study coordination with clinical co-investigators.*

Name: *Brinda Dalal*

Project Role: *Co-Investigator*

Researcher Identifier (e.g. ORCID ID): *N/A*

Nearest person month worked: *12*

Contribution to Project: *Development of qualitative methodology; development of project plan grid; exploration of audio-visual equipment to accommodate VA requirements; facilitating development of working definition of “activity” to drive semi-structured interviews; oversight on study materials (interview guides, tracking sheeting, etc); training of personnel in ethnographic methodology and data analysis approaches.*

Name: *Jeffrey Jaramillo*

Project Role: *Research Manager*

Researcher Identifier (e.g. ORCID ID): *N/A*

Nearest person month worked: *2*

Contribution to Project: *Administrative support*

Name: *Ramya Gopalan*

Project Role: *Study Coordinator*

Researcher Identifier (e.g. ORCID ID): *N/A*

Nearest person month worked: *10*

Contribution to Project: *Development of participant recruiting, screening and enrollment materials. Maintenance of study regulatory materials for research compliance. Participation in interviews and data analysis and interpretation.*

Name: *Jessica Greene*

Project Role: *Research Assistant*

Researcher Identifier (e.g. ORCID ID): *N/A*

Nearest person month worked: *5*

Contribution to Project: *Assist with recruiting materials, building community resource database and data management. Participation in interviews and data analysis. As a person with a SCI, she provides valuable consumer input related to study activities.*

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Beatrice Jenny Kiratli (PI) – No changes in Active Other Support since last year.

Completed Support:

Project Title: Predictive Outcome Model over Time for Employment (PrOMOTE)
Time Commitment: 1.2 Calendar Months
Supporting Agency: VA Rehab R&D
Role: Co-Investigator

Project Title: Assessing Skeletal Risk during Rehabilitation in Patients after Chronic Disuse
Time Commitment: 0.6 Calendar Months
Supporting Agency: VA Rehab R&D
Role: Co-Investigator

Current Support:

Project Title: Evaluating Neural Adaptation after Tendon Transfer and Task-Based Training in SCI
Time Commitment: 0.6 Calendar Months
Supporting Agency: VA Rehab R&D
Agency Contact: Audrey Kusiak
Performance Period: 7/1/15 – 6/30/17
Level of Funding: \$197,203
Project Goals: The purpose of the study is to obtain pilot data consisting of functional magnetic resonance imaging (fMRI) and functional performance measures to evaluate neural predictors and correlates of successful muscle re-education after tendon transfer.

PI: Johanson
Role: Co-Investigator
Overlap: None

Project Title: Exoskeletal-Assisted Walking in Persons with SCI: Impact on Quality of Life
Time Commitment: 1.2 Calendar months
Supporting Agency: VA Cooperative Studies Program Protocol #2003
Agency Contact: Grant Huang, PhD Acting Director of CSP
Performance Period: 10/01/2015 to 9/30/2016 (only year 1 is approved so far)
Level of Funding: \$4,000,000 (Year 1)
Project Goals: This 10-site randomized trial will evaluate whether Veterans with chronic SCI who use an exoskeletal-assisted walking (EAW) device in the home and community environments experience clinically meaningful improvement in patient-reported outcomes related to mental health, bladder, bowel, and pain compared with those who do not use an EAW device.

PI: Spungen (Bronx VA) / Local Site PI: Ota
Role: Local Site Co-Principal Investigator
Overlap: None

What other organizations were involved as partners?

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

- 9. APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.